

**REMARKS**

A check for the fee for three month extension of time accompanies this response. Any fees that may be due in connection with filing this paper or with this application may be charged to Deposit Account No. 50-1213. If a Petition for Extension of time is needed, this paper is to be considered such Petition.

Claims 1-37, 49-54, 93-95 and 99 are pending in this application. Claims 2-4 and 25 are amended to correct inadvertent minor obvious errors. The requirement for Restriction as between groups I and III continues to be traversed; if it is maintained, Applicant reserves the right to file a petition. The election of species as set forth also is traversed.

**Traversal of the Requirement for Restriction**

Applicant respectfully traverses the requirement for restriction as between Groups I and III. It is respectfully submitted that groups III and I are each related as a combination/subcombination for which a showing of two-way distinctness is required.

**Groups I and III**

As stated previously, inventions that are related as a combination and subcombination are distinct and restriction may be proper **only** if it can be shown that the combination as claimed does not require the particulars of the subcombination as claimed for patentability **and** that the subcombination has utility by itself or in other combinations. See MPEP 808.05(c).

In this instance, the combination (group III) requires the particulars of the subcombination for patentability. Therefore, two-way distinctness does not exist. Group III, claims 49-54, is directed to a system (the combination) that comprises the combinations (the subcombination) of Group I. Claims 49 and 50 and claims dependent thereon (group III) are directed to systems for sorting collections of molecules that include a combination of group I, and software for analyzing the results of the sorts. If the combinations of group I are deemed novel and unobvious, the systems of Group III are necessarily novel and

**U.S.S.N. 09/910,120**

**Ault-Riche *et al.***

**ELECTION AND PRELIMINARY AMENDMENT**

unobvious. Therefore, the systems of Group III (the combination) and the combinations of Groups I (the subcombinations) are not distinct.

**Rebuttal to the comments of the Examiner with respect to groups III and I**

The Examiner urges that different patentability considerations are involved for each group. The Examiner states that a patentability determination of group III involves determination of the patentability of a system; while that for Group I involves a consideration of the patentability of the combination of the capture agents and the oligonucleotides. Applicant respectfully disagrees.

Group I is directed to a combination of capture agents and oligonucleotides. Patentability is based on the novelty and unobviousness of a combination of these elements. Group III is directed to a system that includes a combination of group I, and a computer system with software for analyzing the results of sorts. Patentability can be based on the novelty and unobviousness of the combination of capture agents and oligonucleotides. Only if the Examiner determines that a combination of capture agents that encode pre-selected polypeptides and oligonucleotides that encode the pre-selected polypeptides is not novel, will the basis for patentability of groups I and III require different considerations. At this point in the prosecution, Group III requires the particulars (*i.e.*, the combinations of group 1) of claim 1 for patentability. If the combinations of group I are deemed patentable then the systems of group III are patentable.

Furthermore, as noted in the last response, if the claims are restricted into these two groups, applicant ultimately could be granted two patents, one that includes claims directed to the combinations of group II and another with claims directed to systems that include the combinations of group I, that expire on different dates. If the claims to the subcombination (group I) issued first, a later issuing patent encompassing the systems (Group III; the combination) could not be held to constitute obvious-type double patenting over the earlier issuing patent. See MPEP 806, paragraph 3, which states:

**U.S.S.N. 09/910,120**

**Ault-Riche *et al.***

**ELECTION AND PRELIMINARY AMENDMENT**

[w]here inventions are related as disclosed but are not distinct as claimed, restriction is never proper. Where restriction is required by the Office double patenting cannot be held, and thus, it is imperative the requirement should never be made where related inventions as claimed are not distinct.

See, also MPEP 804.01, which states:

35 U.S.C. 121 authorizes the Commissioner to restrict the claims in a patent application to a single invention when independent and distinct inventions are presented for examination. The third sentence of 35 U.S.C. 121 prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application, if the divisional application is filed before the issuance of the patent. The 35 U.S.C. 121 prohibition applies only where the Office has made a requirement for restriction. The prohibition does not apply where the divisional application was voluntarily filed by the applicant and not in response to an Office requirement for restriction. This apparent nullification of double patenting as a ground of rejection or invalidity in such cases imposes a heavy burden on the Office to guard against erroneous requirements for restrictions where the claims define essentially the same invention in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.

As noted above, if the combinations of Group I are deemed free of the prior art, then the systems of Group III, which include the combinations of Group I, will necessarily be free of the prior art. Since restriction of such Groups is improper, reconsideration and withdrawal of the restriction requirement as between Group I and Group III are, therefore, respectfully requested.

**Traverse of the election of species**

The Office Action now requires election of a single species and request election of:

- a. A capture agent.
- b. A specific oligonucleotide compound by defining the length of the oligonucleotide and its components.

The Action states that response to the above election requirement must include an identification of the elected oligonucleotide components and the point of

**U.S.S.N. 09/910,120**

**Ault-Riche *et al.***

**ELECTION AND PRELIMINARY AMENDMENT**

attachment to the capture agent with these requirements, and a listing of all claims readable thereon, including any claims subsequently added.

It is respectfully submitted that the requirement is incorrect for several reasons. First, the oligonucleotides are not attached to the capture agent, and second, it makes no sense to elect a single capture agent or single oligonucleotide, since the claims are directed to combinations that include collections of each. Even if a particular oligonucleotide or capture agent is not novel, it is not relevant to a determination whether a combination of a collection of capture agents and a collection of oligonucleotides that encode polypeptides to which the capture agents bind is novel.

Nevertheless, to the extent possible, Applicant has endeavored to comply and has elected antibodies as capture agents and specified that the oligonucleotides include E<sub>m</sub> regions that are at least 16 nucleotides in length. If the combination of these oligonucleotides are patentable, then a combination that contains oligonucleotides with additional regions specified must necessarily be patentable. Thus, Applicant has elected an oligonucleotide that contains a sequence of nucleotides that encodes a polypeptide to which a capture agent binds. The size of the encoded polypeptide is determined by the number of amino acids that are needed to specifically bind to an antibody, which as described in the application is generally about 3 to 10 amino acids. In the effort to comply, oligonucleotides that contain an "E<sub>m</sub>" region of at least about 16 nucleotides are elected.

The claims are directed to combinations of sets of capture agents and sets of oligonucleotides, such that the oligonucleotides encode the polypeptides to which the capture agents bind. As defined in the specification a combination is an association between or among two or more elements. In this instance the set of capture agents is associated with a set of oligonucleotides (*e.g.*, as part of a kit). The claim sets forth a specific relationship between the two sets (*i.e.*, the oligonucleotides are primers that encode the polypeptides to which the capture agents bind). Thus election of a capture agent constrains the oligonucleotides.

**U.S.S.N. 09/910,120**

**Ault-Riche *et al.***

**ELECTION AND PRELIMINARY AMENDMENT**

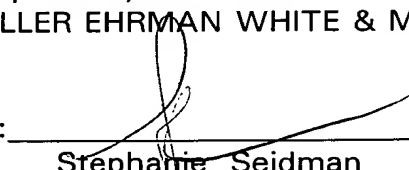
Furthermore, the capture agents are not attached to the oligonucleotides, which serve as primers and are for adding the encoded polypeptide tag to which a capture agent binds, to polypeptides encoded by members of the library.

These combinations are intended for use in the methods of the application in which the oligonucleotides serve as primers and add the encoded polypeptides to members of a sets of sublibraries from a divided library of nucleic acids. Once translated they permit sorting of the encoded members of the library by virtue of their tags and concomitant reduction in diversity of the library when the encoded polypeptides are sorted by the capture agents, where each locus in the collection contains capture agents that bind to the same tag. Screening of the sorted polypeptides identifies loci of interest, thereby identifying the tags and sublibraries of interest. The tags provide a means to identify the oligonucleotides to use for amplification of a sublibrary from which the tagged polypeptides at the loci of interest are derived.

\* \* \*

In view of the remarks herein, reconsideration of the requirement for restriction and examination of all pending claims on the merits are respectfully requested.

Respectfully submitted,  
HELLER EHRMAN WHITE & McAULIFFE LLP

By:   
Stephanie Seidman  
Registration No. 33,779

Attorney Docket No.:25885-1751

**Address all correspondence to:**

HELLER EHRMAN WHITE & McAULIFFE LLP

4350 La Jolla Village Drive, 6th Floor

San Diego, CA 92122

Telephone: 858 450-8400

Facsimile: 858 587-5360

email:sseidman@HEWM.com